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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,358	07/11/2003	Robert M. Pilliar	14396	1521
293 7590 05/21/2008 Ralph A. Dowell of DOWELL & DOWELL P.C. 2111 Eisenhower Ave Suite 406 Alexandria, VA 22314			EXAMINER LOPEZ, CARLOS N	
			ART UNIT 1791	PAPER NUMBER
			MAIL DATE 05/21/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### Office Action Summary

**Application No.**

10/617,358

**Applicant(s)**

PILLIAR ET AL.

**Examiner**

Carlos Lopez

**Art Unit**

1791

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 and 81 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-34 and 81 is/are allowed.
- 6) ☒ Claim(s) 5-27, 29, 35-39, 41, 42 and 44-46 is/are rejected.
- 7) ☒ Claim(s) 28, 30, 40 and 43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-949)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_



***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "held at that temperature" makes it unclear which temperature is being referred.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-14 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Filiaggi et al (On the Sintering of Calcium Phosphates). Filiaggi discloses a method of sintering porous calcium polyphosphate (CPP) to be used as implant tissue. The method comprises forming CPP as detailed in Page 172 of Filiaggi, and then packing the CPP into a Pt(10%Rh) tubes to produce a porous CPP packed body. The packed CPP is then gravity sintered prior to subsequent sintering in a muffle furnace under ambient atmosphere. As noted by Filiaggi the CPP is subjected to a final maximum sintering temperature of 950°C from a temperature of 500°C at a heating rate of 1°C/m



Art Unit: 1791

to 30°C/min. As further noted by Filiaggi the glass transition and crystallization temperature is 530°C and 650°C respectively.

Thus in view that the a sintering of the CCP is done from 500°C to 950°C, and mirrors applicant's sintering methodology as disclosed in Page 37 of the instant specification, it is deemed as that a pre-sintering is done at the claimed specified temperature as the CPP is heated to its final sintering temperature of 950°C.

Additionally, as noted by Filiaggi, the CPP is held at a temperature of 950°C, which is above its crystallization temperature but below its melting point as instantly claimed, for 2 hours prior to being furnace cooled (deemed as the claimed annealing) wherein the resultant CCP is observed to be of crystallized form as disclosed in the Results section of Filiaggi.

As for claimed 6 and 13, the CPP powders do have a predetermined size as noted in page 172 of Filiaggi, thus a predetermined chain length.

As for claims 7-11, see above.

As for claim 12, Filiaggi discloses a density in the range of 55to 75% at page 172.

As for claim 14, the claimed method of making the CPP is disclosed at the first full paragraph of page 172 in Filiaggi.

As for claim 29, Filiaggi notes that crystallization is depended on the RH, see last paragraph of page 172.



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-27,35-39,41-42, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filiaggi et al (On the Sintering of Calcium Phosphates) in view of Kandel et al (US 6,077,989). Filiaggi is silent using dopants on the CPP. However, Kandel teaches of coating the CPP with surface agents such as TiO<sub>2</sub> and iron oxide (See Col.8, lines 57ff) in order to decrease the degradation of the CPP. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have added the disclosed dopants onto the CPP of Filiaggi, as taught by Kandel, in order to decrease the degradation of the CPP that forms the implant tissue.

While Kandel does not disclose the amount of metallic element added to the CPP, it would be obvious to a person of ordinary skill in the art to have conducted routine experimentation to determine the optimum metallic content to be added that would provide for sufficient prevention degradation of the CPP implant.

As for claim 19, the dopant of Kandel would be expected to provide the claimed effect.

As for claim 22, the metallic oxide when sintering of the CPP occurs would be converted to metallic ions.



As for claims 23-24, while Kandel does not disclose the amount of metallic element added to the CPP, it would be obvious to a person of ordinary skill in the art to have conducted routine experimentation to determine the optimum metallic content to be added that would provide for sufficient prevention degradation of the CPP implant.

As for claim 35, at lines 22, col 4, Kandel teaches of infiltrating polyglycolide, polylactide, polycaprolactone, and their copolymers in the the crystallized CPP.

As for claims 36, 39,42, the polymer would be expected to provide for a strong covalent bond to the CPP.

As for claims 37-38 and 41, the limitations are drawn to an optional feature not required by the claims.

As for claims 44-45, the resultant composite material would be expected to have the claimed properties in view that the method claims mirrors the claimed invention.

As for claim 46, Kandel at line 62ff, Col. 9, notes that CPP can be shaped into any suitable shape.

As for claim 15-16, Kandel teaches of sintering in a PT, Filiaggi teaches of sintering in a furnace. Hence, both teachings provide for alternate sintering sites without any unexpected results and reasonable expectation of success. Hence, the claimed sintering environment would have been obvious to a person of ordinary skill in the art at the time the invention was made, in order to sinter the CPP through alternate means.



***Allowable Subject Matter***

Claims 28, 30, 40, and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the primary reason for allowance is that the cited prior art fails to disclose or reasonably suggest a method of forming crystalline bodies comprising the claimed steps of packing, presintering, and annealing in combination with the limitations of the above noted dependent claims.

***Response to Arguments***

Applicant's arguments filed 9/14/07 have been fully considered but they are not persuasive.

Applicant argues that there is no disclosure of holding the temperature steady for any period of time between the glass transition temperature/glass softening temperature and the crystallization temperature. However, said features are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The claim only requires that the temperature be greater than the glass transition period but lower than the crystallization "for an appropriate period of time". Hence, it does not require holding the temperature steady as alleged by applicant.



As noted by Filiaggi the CPP is subjected to a final maximum sintering temperature of 950°C from a temperature of 500°C at a heating rate of 1°C/m to 30°C/min. As further noted by Filiaggi the glass transition and crystallization temperature is 530°C and 650°C respectively. As the temperature reaches 530 °C, the glass transition temperature, it is then steadily increased at a rate of at least 1 °C/m to the crystallization temperature of 650 °C. Thus, the claimed "appropriate period of time" is deemed as the time spent when the temperature is between the transition temperature and the crystallization temperature.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is 571.272.1193. The examiner can normally be reached on Mon.-Fri. 8am - 5pm.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on 571.272.1189. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos Lopez/  
Primary Examiner  
Art Unit 1791